REMARKS

Claims 3, 5-7, and 15 have been cancelled. Claims 1, 2, 4, 8, 12, and 13 have been amended. New claim 22 is added. Claims 1-2, 4, 8-14 and 16-22 are now pending in this application. Claims 16-21 are withdrawn from consideration. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Information Disclosure Statement

In response to paragraph 3, Applicants take notice that references not listed on form PTO-892 or on form PTO-1449 have not been considered by the Examiner as prior art.

Applicants note that an Information Disclosure Statement which was submitted on January 30, 2004 has not been considered by the Examiner. Applicants resubmit this Information Disclosure Statement herewith.

Regarding the Information Disclosure Statement of Paper No. 4, U.S. Patent 6,323,321 B1 which the Examiner has kindly indicated as considered, is the English equivalent of the German patent document DE 197 08 877C1.

Regarding the Information Disclosure Statement of 11/6/01, Applicants resubmit the two references which were not attached to the Information Disclosure Statement and were not available to the Examiner. EP 0596479 & Thomas T, et al. are provided herewith as Attachment A.

Specification

The specification has been amended to correct typographical errors and to indicate that SEPHAROSE is a trademark.

Abstract

A substitute Abstract is submitted herewith on a separate sheet. The terms "said", "concerns" and "and/or" have been avoided.

Claim objections

Claim 8 is objected to under 35 U.S.C. § 1.75(c) as failing to further limit the subject matter of a previous claim.

This objection is traversed by amendment of claim 8. Support for the amendment is found in paragraph 0040 of the published application, for example.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-15 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. & B. Claims 1 and 15 are rejected as it is not clear if the surface structure on the cells will bind one antibody, two antibodies or only antibody 97A6 and because the term "capable of binding" is vague and indefinite.

This ground of rejection is moot with regards to claim 15 which has been canceled.

Claim 1 has been amended to clarify that the cells are contacted with antibody 97A6. The phrase "capable of binding" has been deleted.

C. The rejection of claim 6 is moot in view of Applicants' cancellation of claim 6.

D. Claim 8 has been amended as discussed above in the objection to claim 8. Applicants state that the method for analyzing hematopoiesis could be one of several in the art and is at the discretion of the skilled person.

E. Claim 12 has been amended to delete the term "usual". This term is replaced with "such as ELISA or FACS analysis" to specify methods which are well known immunological detection methods. Support for the amendment is found in paragraph 0047 of the published application. Examples of well known immunological methods are also provided by the specification.

Claims 1-15 are rejected under 35 U.S.C. § 112, second paragraph as being incomplete for omitting essential steps.

Claims 1-15 have been amended to recite active process steps. Support for amendments to claim 1 are found particularly in paragraphs 0077, 0082, 0085, 0089, and 0097 of the published application. Support for amendments to claim 2 may also be found in these paragraphs. See particularly paragraph 0077 at line 7 where "separating" is achieved by washing and at line 12, and where detection of the complex is achieved by means of a flow cytometer.

Support for amended claim 8 is found in paragraph 0040 as discussed above.

Support for amended claim 12 is found in paragraph 0047 as discussed above.

Support for new claim 22 is found in canceled claim 15.

In view of Applicants' amendments and comments, reconsideration and withdrawal of all grounds of rejection under 35 U.S.C. § 112, second paragraph is respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 1-6 and 8-15 are rejected under 35 U.S.C. § 112, first paragraph as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) has possession of the claimed invention at the time that the application was filed.

This rejection is believed to be obviated by Applicants' claim amendments. The present claims are now limited to antibody 97A6.

In view of Applicants' amendments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Claims 1-6 and 8-15 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably provide description of or enablement for the utility of any and every antibody population specific for binding basophils, mast cells, precursor cells of basophils, and precursors of mast cells other than antibody 97A6 produced by hybridoma deposited as No. DSM ACC 2297.

The claims are now limited to antibody 97A6. Consequently, this ground of rejection may be withdrawn.

Claim 7 is rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which is not described in the specification in such a way so as to enable one skilled in the art to which it pertains to make and/or use the invention.

The Examiner asserts that the specification is not enabled for the monoclonal antibodies because antibody 97A6 produced by the hybridoma deposited as No. DSM ACC 2297 has not been deposited under the provisions of the Budapest Treaty.

However, page 5, first paragraph, of the present specification clearly states that the hybridoma producing antibody 97A6 has been deposited under the terms of the Budapest Treaty on February 12, 1997. In addition, the undersigned states that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this Application and the

deposit will be replaced if viable samples cannot be dispensed by the depository. The specification has been amended accordingly.

In view of Applicants' amendment and the above statement, withdrawal of the above ground of rejection is respectfully requested.

Rejection under 35 U.S.C. § 102(e)

Claims 1, 5-7, 10-12 and 15 are rejected under 35 U.S.C. § 102(e) as being anticipated by Buhring (U.S. Patent No. 6,323,321) as evidenced by Blom et al. and Hermine, et al.

The Office Action states that Buhring discloses antibody 97A6 produced by the hybridoma deposited under No. DSM ACC 2297 and that the antibody is taught to be useful in antigen binding on various cell lines including megakaryocytic cell line UT-7. While the patent is silent with respect to binding of basophil cells, mast cells or their precursors, the Office Action asserts that Hermine, et al disclose the UT-7 cell line as having basophil cells while Blom et al disclose that the KU812 cell line has mast and basophil cells.

Applicants assert that the subject matter of amended claim 1 and of claims depending thereon is not anticipated by the cited prior art documents.

Buhring teaches that the antibody 97A6 is capable of binding to cell lines UT-7 and KU812. These cell lines are leukemic cell lines, which do not include mast and basophil cells.

This statement is supported by both prior art references cited by the Examiner. Hermine et al. disclose that the UT-7 cell line will differentiate into a cell line having basophilic features only in the presence of growth factors, such as GM-CSF and IL-3. This, in reverse, means that the untreated UT-7 cell line is not a basophil cell line nor does it include corresponding cells.

Similarly for cell line KU812, as taught by Blom et al., KU812 cells are induced for basophilic differentiation by several inducers, such as serum starvation; cf. abstract before last sentence. It goes without saying that a cancer cell line, such as KU812, expresses a number of surface proteins like mast cell and basophil-related proteins. But a cancer cell line differs from mast or basophilic cells which are highly differentiated and specialized cells.

Accordingly, Buhring does not anticipate the present claims because Buhring does not teach the method step of binding antibody 97A6 to a basophil or mast cell. As discussed above, the cell lines disclosed by Buhring do not include basophil or mast cells.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Rejection under 35 U.S.C. § 103(a)

Claims 2-4, 8-9, and 13-14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Buhring (U.S. Patent No. 6,323,321) in view of Irsch, et al. (WO 97/46880).

As discussed above, while Buhring teaches the binding of the antibody 97A6 to leukemic cells, Buhring does not teach or suggest the binding of 97A6 to basophil or mast cells. Both UT-7 and KU812 cell lines are cancer cell lines that do not have characteristics of basophil or mast cell lines in the absence of inducers such as serum starvation. Accordingly, there was no motivation in Buhring to use the 97A6 antibody for the binding of either mast cells or basophil cells and no reasonable expectation of success.

Document WO 97/46880 does not add any information to the disclosure of Buhring which challenges the inventive skill of the present invention since no antibody is disclosed which can be compared to the antibody 97A6 of the present claims.

Therefore, the art neither anticipates the finding of the inventors that the deposited antibody is capable of binding to basophils, mast cells and precursor cells thereof, nor makes such a capability obvious.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of this ground of rejection is respectfully requested.

CONCLUSION

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 9, 2004

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